P/546-280

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Confirmation No.: 2921
Nozer M. Mehta, et al.	Date: March 18, 2010
Serial No.: 10/761,481	Group Art Unit: 1654
Filed: January 20, 2004	Examiner: Jeffrey E. Russel

For: IMPROVED ORAL DELIVERY OF PEPTIDES

VIA EFS-WEB
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

On p. 2 of the Office Action dated September 18, 2009 the Examiner cites to Paragraph 6 of the Declaration Under 37 C.F.R. §1.132 by Inventor Stern dated July 28, 2009 and to p. 16, lines 1-4 in the Remarks submitted in the "Amendment Under 37 C.F.R. §1.116 filed on of even date therewith. The Examiner points out that the Declaration and the Remarks state that naturally occurring LHRH is not amidated at its C-terminus and that LHRH that is amidated at its C-terminus is amidated at a location that is not naturally amidated. The Examiner then cites several publications that demonstrate that the indicated statements are not technically correct.

Applicants acknowledge that, in fact, naturally occurring LHRH is amidated at its C-terminus and that LHRH amidated at its C-terminus is not amidated at a location that is not naturally amidated. Applicants apologize for any confusion caused due to the above-identified misstatements and submit that they were based on a misunderstanding between applicants and their counsel, as explained below.

The misunderstanding concerns the results set forth in Example 4 at pp. 57-59 in the present specification. The Experiment was carried out by Inventor Stern to demonstrate that amidated LHRH has greater bioavailability than LHRH that is not amidated. It has now been clarified to Applicants' counsel that the inventor obtained, for purposes of comparison, commercially available non-amidated LHRH (i.e., wherein the C-terminal amino acid is gly-

COOH instead of gly-NH_2) and then compared the effect of this material with that of natural LHRH which was, in fact, amidated at the C-terminus. Thus, since one of the LHRH peptides was not amidated, applicants' counsel mistakenly deemed the non-amidated LHRH to be natural LHRH and the 'natural', i.e., amidated peptide thus became characterized as LHRH amidated at a location that is not naturally amidated.

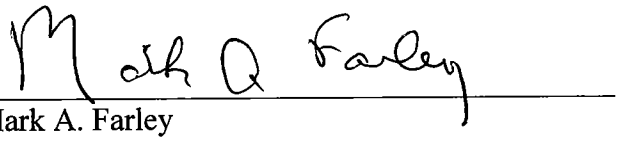
It was due to the above-described misunderstanding, therefore, that the statements noted by the Examiner were made, i.e., that LHRH is not naturally amidated and that the LHRH peptide which was in fact amidated was amidated at a location that is not naturally amidated. Applicants and their counsel now recognize that the above statements were incorrect and they regret any confusion caused thereby. The Examiner is, moreover, thanked for pointing out the discrepancy. This Information Disclosure Statement is, thus, being submitted for the purpose of clarifying the record with regard to the structure and characteristics of the naturally occurring LHRH peptide.

No fee is believed to be due with this submission. However, if any fee is due, authorization is hereby provided to charge the required fee to Deposit Account No. 15-0700.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON March 18, 2010.

MAF:ck

Respectfully submitted,



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